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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/051,311

01/22/2002

Jan-Michael Peters

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07/12/2007

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

1100 NEW YORK AVENUE, N.W.

WASHINGTON, DC 20005

EXAMINER

FRONDA, CHRISTIAN L

ART UNIT

PAPER NUMBER

1652

MAIL DATE

DELIVERY MODE

07/12/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--|--------------------------------------|--|
| Office Action Summary | Application No. 10/051,311 | Applicant(s) PETERS ET AL. | |
| | Examiner Christian L. Fronda | Art Unit 1652 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 11-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 11-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/04/2007 has been entered.
2. Claims 1-6 and 11-16 are pending and under consideration in this Office Action.
3. The rejection of claims 1-5 and 11-15 under 35 U.S.C. 112, first paragraph, as failing to meet the enablement requirement has been withdrawn in view of applicants' arguments and amendment dated 06/04/2007.
4. The rejection of claims 1-5 and 11-15 under 35 U.S.C. 112, first paragraph, as failing to meet the written description requirement has been withdrawn in view of applicants' arguments and amendment dated 06/04/2007.

Claim Rejections - 35 U.S.C. § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
6. Claims 1-5 and 11-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al. (Anal Biochem. 1994 Feb 15;217(1):139-47; reference AT cited in PTO 1449 dated 11/19/2002) in view of the combined teachings of Nagase et al. (DNA Res. 1996 Feb 29;3(1):17-24), Nomura et al. (DNA Res. 1994; 1(5):223-9), and Zou et al. (Science. 1999 Jul 16;285(5426):418-22).

Brown et al. teach a high-throughput fluorometric process for measuring protease activity

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comprising contacting a flurogenic peptide labeled at one end with a UV/blue fluorophore and at the other end a quencher in the presence of an inhibitor test compound (see entire publication, especially **Discussion** section on pp. 145-147). Brown et al. does not teach incubating with a test compound a separin in the presence of a separin substrate.

Nagase et al. teach the cDNA KIAA0165 (see entire publication, especially Table 1 on p. 19). Waizenegger et al. (Cell. 2000 Oct 27;103(3):399-410) provide evidence that KIA0165 is the human separin, which is the protease for human SCC1 and is involved in sister chromatid separation (see entire publication, especially p. 408, left column, lines 6-28; and p. 409, right column, line 26). Thus, Nagase et al. teach the human separin encoded by cDNA KIAA0165.

Nomura et al. teach the cDNA KIAA0078 (see entire publication, especially Table 1 on p. 226). Sumara et al. (J Cell Biol. 2000 Nov 13;151(4):749-62) provide evidence that KIAA0078 is the human SCC1 (see entire publication, especially p. 750, right column, section titled *cDNA Clones*, lines 37-38). Thus, Nomura et al. teach the human SCC1 (a separin substrate) encoded by cDNA KIAA0078 which comprises SEQ ID NO: 9.

Zou et al. teach the human securing which is a vertebrate sister-chromatid separation inhibitor involved in transformation and tumorigenesis and *Xenopus* egg extracts used in activating separase (see entire publication).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the process of Brown et al. such that the human separin taught by Nagase et al., the human SCC1 taught by Nomura et al., and securing taught by Zou et al. is used in the process taught by Brown et al., where the human SCC1 is labeled at one end with a UV/blue fluorophore and at the other end a quencher. One of ordinary skill in the art at the time the invention was made would have been motivated to do this for the purposes of having a fast and simple process for identifying human separin inhibitors, which can be used as anti-cancer agents that inhibit sister chromatid separation in cancer cells.

No patentable weight is given to the preamble of these process claims since it merely recites the purpose of these process claims. Thus, the process steps of the modified Brown et al. process stated above renders the claims obvious because these process steps are the same as the process steps of the claims. Because the process steps of the modified Brown et al. process stated above are the same as the process steps of these claims, then the modified Brown et al. process would inherently identify compounds that inhibit sister chromatid separation in eukaryotic cells.

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Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-6 and 11-16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 36-59 of copending Application No. 09/500,991. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter of the invention of claims 36-59 of copending Application No. 09/500,991 are fully encompassed and therefore anticipates claims 1-6 and 11-16 of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

9. No claim is allowed.


10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The

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examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF



PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1652